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10533160
File   5:Biosis Previews(R) 1926-2008/May W4
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      Set  Items  Description
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? s albumin and pasteur?
          124435  ALBUMIN
           40033  PASTEUR?
       S1     246  ALBUMIN AND PASTEUR?
? s s1 and ((fraction()V) or (paste()V))
             246  S1
          255268  FRACTION
          528626  V
             466  FRACTION(W)V
            7608  PASTE
          528626  V
               0  PASTE(W)V
       S2      1  S1 AND ((FRACTION()V) OR (PASTE()V))
? t s2/7/1

 2/7/1
DIALOG(R)File   5:Biosis Previews(R)
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0001081056   BIOSIS NO.: 19603500063495
Growth stimulation of %%%Pasteurella%%% pestis by a combination of coconut
  water and %%%albumin%%% complex
AUTHOR: PITAL ABE
JOURNAL: JOUR BACT  79 ((6)): p905-906 1960 1960
DOCUMENT TYPE: Article
RECORD TYPE: Abstract
LANGUAGE: Unspecified

ABSTRACT: Utilizing a basal medium of heart infusion broth (Difco) plus
  added calcium ion (0.004[image]) and xylose (0.2%), a variety of
  nutrients was tested for growth stimulating activity of small inocula of
  P. pestis (virulent and avirulent). Among a number of substances tested
  to date, only the combination of coconut water (4%) and Dubos oleic
  %%%albumin%%% complex.(Difco - 0.1% %%%albumin%%% %%%fraction%%% %%%V%%%)
  markedly stimulated the growth of small inocula approximately 10 cells
  per ml). The degree of stimulation varied with different strains. A
  10-80-fold increase in cell numbers was obtained over the basal medium
  during a 29 hr. period of incubation with aeration at 37oC. ABSTRACT
  AUTHORS: Author
? s s1 and cohn
             246  S1
            1590  COHN
       S3      7  S1 AND COHN
? t s3/7/1-7

 3/7/1
DIALOG(R)File   5:Biosis Previews(R)
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19079854   BIOSIS NO.: 200600425249
Botulinum toxin type A therapy and human serum %%%albumin%%% - Reply
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AUTHOR: Cetnarowski Wes (Reprint); Dadas Chris
AUTHOR ADDRESS: Allergen Inc, Irvine, CA USA**USA
AUTHOR E-MAIL ADDRESS: dadaschristopher@allergan.com
JOURNAL: Anesthesiology (Hagerstown) 104 (5): p1108-1109 MAY 2006 2006
ISSN: 0003-3022
DOCUMENT TYPE: Letter; Editorial
RECORD TYPE: Citation
LANGUAGE: English

3/7/2
DIALOG(R)File 5:Biosis Previews(R)

16295450 BIOSIS NO.: 200100467289
Isolation of bovine plasma %%%albumin%%% by liquid chromatography and its polymerization for use in immunohematology
AUTHOR: Tanaka K (Reprint); Sawatani E; Shigueoka E M; Dias G A; Nakao H C; Arashiro F
AUTHOR ADDRESS: Divisao de Pesquisa e Desenvolvimento Industrial, Fundacao Pro-Sangue Hemocentro de Sao Paulo, Av. Eneas C. Aguiar, 155, 1 andar, 05403-000, Sao Paulo, SP, Brazil**Brazil
JOURNAL: Brazilian Journal of Medical and Biological Research 34 (8): p 977-983 August, 2001 2001
MEDIUM: print
ISSN: 0100-879X
DOCUMENT TYPE: Article
RECORD TYPE: Abstract
LANGUAGE: English

ABSTRACT: The aim of the method described here is to remove hemoglobin, the major contaminant in the bovine plasma obtained from slaughter-houses, by adding a mixture of 19% cold ethanol and 0.6% chloroform, followed by fibrinogen and globulin precipitation by the %%%Cohn%%% method and nonspecific hemagglutinin by thermocoagulation. The experimental volume of bovine plasma was 2,000 ml per batch. Final purification was performed by liquid chromatography using the ion-exchange gel DEAE-Sepharose FF. The bovine %%%albumin%%% thus obtained presented gtoreq99% purity, a yield of 25.0 +- 1.2 g/l plasma and >71.5% recovery. N-acetyl-DL-tryptophan (0.04 mmol/g protein) and sodium caprylate (0.04 mmol/g protein) were used as stabilizers and the final concentration of %%%albumin%%% was adjusted to 22.0% (w/v), pH 7.2 to 7.3. Viral inactivation was performed by %%%pasteurization%%% for 10 h at 60degreeC. The bovine %%%albumin%%% for the hemagglutination tests used in immunohematology was submitted to chemical treatment with 0.06% (w/v) glutaraldehyde and 0.1% (w/v) formaldehyde at 37degreeC for 12 h to obtain polymerization. A change in molecular distribution was observed after this treatment, with average contents of 56.0% monomers, 23.6% dimers, 12.2% trimers and 8.2% polymers. The tests performed demonstrated that this polymerized %%%albumin%%% enhances the agglutination of Rho(D)-positive red cells by anti-Rho(D) serum, permitting and improving visualization of the results.

3/7/3
DIALOG(R)File 5:Biosis Previews(R)

14788547 BIOSIS NO.: 199900048207
Purification of human %%%albumin%%% by the combination of the method of %%%Cohn%%% with liquid chromatography
AUTHOR: Tanaka K (Reprint); Shigueoka E M; Sawatani E; Dias G A; Arashiro F ; Campos T C X B; Nakao H C
AUTHOR ADDRESS: Div. Producao Desenvolimento Industrial Fundacio Pro-Sangue Hemocentro Sao Paulo, Av. Dr. Eneas C. Aguiar 155, 1 andar 05403-000 Sao Paulo, SP, Brazil**Brazil
JOURNAL: Brazilian Journal of Medical and Biological Research 31 (11): p 1383-1388 Nov., 1998 1998
MEDIUM: print
ISSN: 0100-879X
DOCUMENT TYPE: Article
RECORD TYPE: Abstract
LANGUAGE: English

ABSTRACT: Large volumes of plasma can be fractionated by the method of %%%Cohn%%% at low cost. However, liquid chromatography is superior in terms of the quality of the product obtained. In order to combine the advantages of each method, we developed an integrated method for the production of human %%%albumin%%% and immunoglobulin G (IgG). The cryoprecipitate was first removed from plasma for the production of factor VIII and the supernatant of the cryoprecipitate was fractionated by the method of %%%Cohn%%%. The first precipitate, containing fractions (F)-I + II + III, was used for the production of IgG by the chromatographic method (see Tanaka K et al. (1998) Brazilian Journal of Medical and Biological Research, 31: 1375-1381) The supernatant of F-I + II + III was submitted to a second precipitation and F-IV was obtained and discarded. %%%Albumin%%% was obtained from the supernatant of the precipitate F-IV by liquid chromatography, ion-exchange on DEAE-Sepharose FF, filtration through Sephacryl S-200 HR and introduction of heat treatment for fatty acid precipitation. Vital inactivation was performed by %%%pasteurization%%% at 60degreeC for 10 h. The %%%albumin%%% product obtained by the proposed procedure was more than 99% pure for the 15 lots of %%%albumin%%% produced, with a mean yield of 25.0 +- 0.5 g/l plasma, containing 99.0 to 99.3% monomer, 0.7 to t.0% dimers, and no polymers. Prekallikrein activator levels were ltoreq5 IU/ml. This product satisfies the requirements of the 1997 Pharmacopee Europeenne.

3/7/4
DIALOG(R)File 5:Biosis Previews(R)

14696156 BIOSIS NO.: 199800490403
Chromatographic removal and heat inactivation of hepatitis B virus during the manufacture of human %%%albumin%%%
AUTHOR: Adcock Wayne L (Reprint); Macgregor Andrew; Davies Jeff R; Hattarki Meghan; Anderson David A; Goss Neil H
AUTHOR ADDRESS: Res. Dev., CSL Limited, Bioplasma Div., 189-209 Camp Road, Broadmeadows, Victoria 3047, Australia**Australia
JOURNAL: Biotechnology and Applied Biochemistry 28 (2): p169-178 Oct., 1998 1998
MEDIUM: print
ISSN: 0885-4513
DOCUMENT TYPE: Article

RECORD TYPE: Abstract
LANGUAGE: English

ABSTRACT: The purpose of the present study was to examine the efficacy of the chromatographic and %%%pasteurization%%% steps, employed in the manufacture of human %%%albumin%%%, in the removal and/or inactivation of hepatitis B virus (HBV). Most human albumins manufactured today are prepared from donor plasma by fractionation methods that use precipitation with cold ethanol. CSL Limited, an Australian biopharmaceutical company, has recently converted its method of manufacture for %%%albumin%%% from a traditional %%%Cohn%%% fractionation method to a method employing chromatographic techniques. A step-by-step validation of virus removal and inactivation was performed on this manufacturing process, which includes a DEAE-Sepharose and CM-Sepharose Fast Flow ion-exchange step, a Sephacryl S200 HighResolution gel-filtration step and a bulk %%%pasteurization%%% step where product is held at 60degreeC for 10 h. H BV partitioning experiments were conducted on scaleddown chromatographic columns with hepatitis B surface antigen (HBsAg) as a marker, whereas the HBV model virus, duck HBV, was used to study the inactivation kinetics during %%%pasteurization%%%. Reductions for HBsAg through the three chromatographic steps resulted in a total log10 decrease of 1.5 log10 whereas more than 6.5 log10 decrease in duck HBV in Albumex 5 was achieved during %%%pasteurization%%%.

3/7/5

14609534 BIOSIS NO.: 199800403781
Chromatographic removal and heat inactivation of hepatitis A virus during manufacture of human %%%albumin%%%
AUTHOR: Adcock Wayne L (Reprint); Macgregor Andrew; Davies Jeff R; Hattarki Meghan; Anderson David A; Goss Neil H
AUTHOR ADDRESS: Res. and Dev., CSL Ltd., Bioplasma Div., 189-209 Camp Road, Broadmeadows, VIC 3047, Australia**Australia
JOURNAL: Biotechnology and Applied Biochemistry 28 (1): p85-94 Aug., 1998 1998
MEDIUM: print
ISSN: 0885-4513
DOCUMENT TYPE: Article
RECORD TYPE: Abstract
LANGUAGE: English

ABSTRACT: CSL Limited, an Australian biopharmaceutical company, has recently converted its method of manufacture for human %%%albumin%%% from a traditional %%%Cohn%%%-ethanol fractionation method to a method employing chromatographic techniques. Studies were undertaken to determine the efficiency of the chromatographic and %%%pasteurization%%% steps used in the manufacture of Albumex (CSL's trade name for %%%albumin%%%) in removing and inactivating the potential viral contaminant, hepatitis A virus (HAV). The manufacturing process for Albumex includes three chromatographic steps, two of which are ion-exchange steps (DEAE-Sepharose Fast Flow and CM-Sepharose Fast Flow) and the third is a gel-filtration step (Sephacryl S200 HR). The final stage of the Albumex process involves a bulk %%%pasteurization%%% step where product is held at 60 degreeC for 10 h. HAV partitioning

experiments on the DEAE-Sepharose FF and CM-Sepharose FF ion-exchange and Sephacryl S200 HR gel-filtration columns were performed with scaled-down models of the production-scale chromatographic Albumex process. Production samples collected before each of the chromatographic steps were spiked with HAV and processed through each of the scaled-down chromatographic columns. Samples collected during processing were assayed and the log10 reduction factors calculated. Inactivation kinetics of HAV were examined during the %%%pasteurization%%% of Albumex 5 and 20 (5% and 20% (w/v) %%%albumin%%% solutions) held at 60 degreeC for 10 h. Log10 reductions for HAV through the DEAE-Sepharose FF, CM-Sepharose FF and Sephacryl S200 HR chromatographic columns were 5.3, 1.5 and 4.2 respectively, whereas a 4.4 and a greater than 3.9 log10 reduction in HAV in Albumex 5 and 20 respectively were achieved during %%%pasteurization%%%.

3/7/6
DIALOG(R)File 5:Biosis Previews(R)

14520309 BIOSIS NO.: 199800314556
Characterization and viral safety validation study of a %%%pasteurized%%% therapeutic concentrate of antithrombin III obtained through affinity chromatography
AUTHOR: Biescas Herminia; Gensana Marta; Fernandez Jesus; Ristol Pere; Massot Marta (Reprint); Watson Elisabeth; Vericat Fernando
AUTHOR ADDRESS: Lab. Investigacion, Inst. Grifols S.A., Poligono Levante, C/Can Guasch 2, 08150 Parets Valles, Barcelona, Spain**Spain
JOURNAL: Haematologica 83 (4): p305-311 April, 1998 1998
MEDIUM: print
ISSN: 0390-6078
DOCUMENT TYPE: Article
RECORD TYPE: Abstract
LANGUAGE: English

ABSTRACT: Background and Objective. Antithrombin III (ATIII) concentrates are employed as therapy for congenital or acquired deficiencies. These concentrates are obtained from %%%Cohn%%%'s fraction IV1. To improve yields, purity and safety, our group developed a procedure to obtain a %%%pasteurized%%% ATIII concentrate from the supernatant of %%%Cohn%%%'s fraction II+III including a highly efficient heparin affinity chromatography purification and %%%pasteurization%%% as a viral inactivation step. Design and Methods. Three steps of the manufacturing procedure (Crohn's fraction II + III precipitation, affinity chromatography and %%%pasteurization%%%) were selected to examine their efficacy in inactivating and/or removing the selected viruses. Results. The industrial batches show a purity higher than 99% with approximately 95% native heparin binding ATIII. Only %%%albumin%%% and IgG could be detected at trace levels (0.07% and 0.16% of the total protein present, respectively). The specific activity of the product was approximately 6.65 IU/mg protein. Five viruses were spiked into the manufacturing starting materials and samples were collected at various points to determine the infection level of virus. The study showed a reduction factor (log 10) > 11.7 for HIV-1; > 8.1 for bovine herpes virus (analyzed as a model for herpes and hepatitis B viruses); > 8.1 for bovine diarrhea virus (model for hepatitis C and G) and > 6.0 for encephalomyocarditis virus (model for hepatitis A and other non-enveloped viruses).

Interpretation and Conclusions. No biochemical alterations of the ATIII were detected In the final product. A high viral elimination capacity of the production process was demonstrated. So far, more than 32 million units of ATIII have been transfused in the form of this therapeutic concentrate without any detected seroconversion.

3/7/7
DIALOG(R)File 5:Biosis Previews(R)

11921040 BIOSIS NO.: 199396085456
Validation of virus inactivation during a chromatographic purification of human plasmatic %%%albumin%%%
AUTHOR: Stoltz J F (Reprint); Geschier C; Rivat C; Sertillanges P; Grandgeorges M; Liautaud J; Regnault V; Dumont L
AUTHOR ADDRESS: Centre Regional Transfusion Sanguine, CHU Bradois, F54500 Vandoeuvre, France**France
JOURNAL: Annales Pharmaceutiques Francaises 51 (2): p78-93 1993
ISSN: 0003-4509
DOCUMENT TYPE: Article
RECORD TYPE: Abstract
LANGUAGE: French

ABSTRACT: Almost the whole of the human plasma %%%albumin%%% preparations intended for clinical or biological uses is at present fractionated by cold ethanol precipitation technics based on the %%%Cohn%%% method. However, ion-exchange chromatographic processes have been recently developed. The aim of this work was the evaluation of the viral inactivation efficacy of an automated industrial chromatographic process allowing fractionation of 350 to 400 l of plasma per cycle (one precipitation step, three ion-exchange chromatography steps using the Spherodex-Spherosil gels - Sepracor-IBF, Villeneuve la Garenne, France - and one %%%pasteurization%%% step. Three relevant viruses were selected for this validation study : the hepatitis B virus (HBV), the poliomyelitis virus and the human immunodeficiency virus (HIV). In order to comply with EEC and FDA regulatory documents, significant amounts of the tested viruses were spiked into the different fractions obtained during the various purification steps and their removal or inactivation during the subsequent step were determined. The validation study was performed under conditions which mimic the manufacturing process using fractions obtained during a semi-industrial fractionation. Moreover, residual viral infectivity was checked on after elution and washing of the columns for each chromatographic step. Results have pointed out : a) an overall reduction of 4.4 log 10 for HBV. Infectivity is judged by a combination of several markers and the DNA polymerase activity is the most affected particularly during the three ending purification steps; b) an overall reduction in virus titer gt 10 log 10 for the poliomyelitis virus; c) an overall reduction in virus titer gt 10 log 10 for HIV (four of the five steps have an important potential to inactivate this virus increasing the safety of the process). Moreover, no residual viral infectivities were detected after washing of the columns. In conclusion, this study showed the viral safety of human %%%albumin%%% purified using the chromatographic Spherodex-Spherosill process. As had been observed for fractionation by means of ethanol, the %%%pasteurization%%% step is necessary to ensure inactivation of two of the three viruses tested (HBV and poliomyelitis virus). This validation study allowed the preparation

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  of a manufacturing and controls document for %%%albumin%%% and a
  marketing authorization has been issued by the "Laboratoire National de
  la Sante" (LNS, France).
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PLEASE ENTER A COMMAND OR BE LOGGED OFF IN 5 MINUTES
? log y
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            $5.43    0.877 DialUnits File5
              $19.52  8 Type(s) in Format  7
           $19.52  8 Types
    $24.95  Estimated cost File5
     $2.66  TELNET
    $27.61  Estimated cost this search
    $27.63  Estimated total session cost   1.263 DialUnits
Logoff: level 05.22.00 D  06:53:25
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